K080759

MAY 12 2008

510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR § 807.92

1.0 Submitter's Information

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Contact:	Tray Cui
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2.0 Device Information

Name:	Infrared Thermometer
Trade Name:	ThermoFlash LX-26
Model:	ThermoFlash LX-26

3.0 Classification

Product Code:	FLL---clinical electronic thermometer
Regulation Number:	880.2910
Classification:	II
Panel:	80

4.0 Predicate Device Information

Sponsor:	Famidoc Technology Co., Ltd
Device:	Infrared Thermometer, Model: FDIR-V1
510(K) Number:	K052849

5.0 Device description

Infrared Thermometer ThermoFlash LX-26 is a hand held, reusable, battery operated, maximum device that can measure human body surface and forehead

temperature measurement for infants and adults without contact to human body. It can be used by consumers in household environment and doctor in clinic as reference. It is manufactured in accordance with the ASTM 1965-98 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature.

The operation principle is based on infrared sensor technology. IR Sensor can putout different signal when measuring different object temperature or in different ambient temperature. An ASIC can turn the signal from IR sensor to digital value and display it by LCD.

6.0 Intended Use

ThermoFlash LX-26 is an infrared thermometer for body surface and forehead temperature measurement for infants and adults without contact to human body. It can be used by consumers in household environment and doctor in clinic as reference.

7.0 Performance Summary

The device conforms to applicable standards included ASTM E 1965-98(2003), IEC 60601-1 and IEC 60601-1-2 requirements.

8.0 Comparison to predicate device and conclusion

Our Infrared Thermometer ThermoFlash LX-26 is substantially equivalent to Infrared Thermometer, Model: FDIR-V1 whose 510(K) number is K052849.

The two devices are very similar in design principle, intended use, functions, material and the applicable standards. Only their outlook and some parameter such as measurement rang are different. However, the tests in this submission provide demonstration these small differences do not raise any new question of safety or effectiveness.

The infrared thermometer ThermoFlash LX-26 is substantially equivalent to the predicate device.

9.0 Draft date: June 21, 2007

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2008

JXB Company, Limited Guangzhou
C/O Mr. Casey Conry
Responsible Third Party Official
Underwriters Laboratories, Incorporated
1285 Walt Whitman Road
Melville, New York 11747

Re: K080759
Trade/Device Name: ThermoFlash LX-26
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: April 25, 2008
Received: April 28, 2008

Dear Mr. Conry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ThermoFlash LX-26 FDA 510(K) Files K080759

Statement of Indications for Use

510(k) Number (if known):

Device Name: ThermoFlash LX-26

Indications For Use:

ThermoFlash LX-26 is an infrared thermometer for body surface and forehead temperature measurement for infants and adults without contact to human body.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080759